DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 JEH

March 25, 2002

VIA FEDERAL EXPRESS – NEXT DAY

Mr. Walter C. Edge, Jr.
President
Edge Biologicals Inc.
598 North Second Street
Memphis, TN 38105

Warning Letter No. 02-NSV-17

Dear Mr. Edge:

During an inspection of your firm on February 5-11 and March 1, 2002, our investigator determined that your facility manufactures in-vitro diagnostic media that are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed deviations from 21 CFR Part 820 including a failure to validate manufacturing, sterilization and packaging processes, inadequate Standard Operating Procedures, incomplete specifications for different autoclave cycles, failure to calibrate manufacturing equipment, no Quality System Regulation training of firm personnel, no Master Device File, failure to adequately investigate consumer complaints, no investigation of finished device failures, and no verification that incoming raw materials conform to specific requirements.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations identified by the FDA.

We would like to point out that despite your written commitment (your letter dated 05-23-01 and letter dated 06-18-01 and Quality Plan dated 08-03-01 in response to our Warning Letter dated 06-05-01) to correct deficiencies noted during the previous inspection of your firm conducted between May 16-18, 2001, this current inspection revealed 24 separate QSR deviations, including 3 of which were identified during the May 2001 inspection. The only deviations noted during the previous inspection that were adequately corrected by you were the separation of expired media from the in-process and finished product.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject device have been corrected.

We acknowledge your response dated March 6, 2002 to our investigator's observations noted on the From FDA 483 as a result of our February 5-11 and March 1, 2002 inspection. The response is totally inadequate due to the fact that no documents are submitted verifying that improvements have been made and no time frames are given when the corrections will be completed. In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts and Certificates to Foreign Governments for products manufactured at your facility, we are requesting that you submit to this office within six months from the date of this letter certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and Quality Assurance Systems relative to the requirements of the Quality System Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by you that your establishment has initiated or completed all corrections called for in the report.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District

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